Application No. 09/560,597
Filed: April 28, 2000
Group Art Unit: 3626

In the Claims

Please cancel claims 15 and 19 without prejudice or dedication.

Please rewrite the indicated claims to read as follows:

1. A method of conducting a clinical trial of a test substance over the internet from a primary site, comprising the following steps:

assigning, at the primary site, a unique identifier and a unique log-in password to at least one clinical trial participant located at a remote internet site distinct from the primary site, the unique identifier and the unique log-in password for accessing protected information from the primary site;

providing to the participant, responsive to receipt by the primary site of the unique identifier and the unique log-in password, instructions on: using the test substance; accessing and completing at least one evaluation form from a website maintained at the primary site; and returning electronically said at least one evaluation form to the primary site;

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providing, responsive to receipt by the primary site of the unique identifier and the unique log-in password, said at least one evaluation form in electronic format for use by the participant, said at least one evaluation form having a question and answer section that, when completed by a participant using the test substance, provides information from which a determination can be made of one or more effects of the test substance on the participant completing the evaluation form; and

A1

compiling data regarding at least one said effect of the test substance on the participant from information from a received and completed evaluation form returned by the participant to at least one investigator conducting the clinical trial.

8. A method of conducting a clinical trial of a test substance over the internet, comprising the following steps:

- maintaining, at a primary site, a website that is accessible from remote sites via the internet and that provides information about the clinical trial and minimum eligibility criteria for participants in the clinical trial;

A2

- causing a screening questionnaire to appear over the internet at a remote site, after receipt, at the primary site from

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the remote site, of a request to display the questionnaire, wherein the questionnaire has portions for receiving information that enables a determination of whether a candidate, upon whose behalf the questionnaire is completed, is eligible to be a participant in the clinical trial;

- obtaining the candidate's informed consent to participate in the clinical trial;

- receiving the candidate's completed questionnaire at the primary site via the internet;

- reviewing the received questionnaire and making a determination of whether the candidate is eligible to be a participant in the clinical trial according to a set of predetermined criteria;

- after receipt of the candidate's informed consent by at least one investigator, causing information transfer between the primary site and the remote site for the purpose of confirming the existence, identity, and eligibility of the candidate to participate;

- assigning, at the primary site, a unique identifier and a unique log-in password to at least one clinical trial participant, the unique identifier and the unique log-in password for accessing protected information from the primary site;

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- providing, responsive to receipt by the primary site of the unique identifier and the unique log-in password, to the participant, instructions on: using the test substance; accessing and completing at least one evaluation form from a website maintained at the primary site; and returning electronically said at least one evaluation form to the primary site;

- providing, responsive to receipt by the primary site of the unique identifier and the unique log-in password, said at least one evaluation form in electronic format for use by the participant, said at least one evaluation form having a question and answer section from which a determination can be made of one or more effects of the test substance on the participant completing the evaluation form; and

- compiling data regarding at least one said effect of the test substance on the participant from information from a received and completed evaluation form returned by the participant to at least one investigator conducting the clinical trial.

13. The method of claim 1, 2, 7, or 8, further comprising collecting and storing at a secure site accessible by the at least one investigator and by the participant, information from at least one member of the group consisting of: at least one evaluation form completed and returned by the participant to the at least one

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Q3 investigator; and a screening questionnaire completed and returned by the participant to the at least one investigator.

29. A system for conducting a clinical trial of a test substance over the internet from a primary site, comprising at least one computer at the primary site that comprises:

program code for assigning, at the primary site, a unique identifier and a unique log-in password to at least one clinical trial participant located at a remote internet site distinct from the primary site, the unique identifier and the unique log-in password for accessing protected information from the primary site;

Q4 program code for providing, via the internet, responsive to receipt by the primary site of the unique identifier and the unique log-in password, to at least one clinical trial participant located at a remote site distinct from the primary site, instructions on: using the test substance; accessing and completing at least one evaluation form from a website maintained at the primary site; and returning electronically said at least one evaluation form to the primary site;

program code for providing, responsive to receipt by the primary site of the unique identifier and the unique log-in password, said at least one evaluation form in electronic format

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for use by the participant at the remote site, said at least one evaluation form having a question and answer section that, when completed by a participant using the test substance, provides information from which a determination can be made of one or more effects of the test substance on the participant completing the evaluation form; and

a4 program code for compiling into a central database at the primary site, data regarding at least one said effect of the test substance on the participant from information from a received and completed evaluation form returned by the participant to at least one investigator conducting the clinical trial.

38. The system of any of claims 29-36, further comprising means for collecting and storing at a secure site accessible by the at least one investigator and by the participant, information

a5 from at least one member of the group consisting of: at least one evaluation form completed and returned by the participant to the at least one investigator; and a screening questionnaire completed and returned by the participant to the at least one investigator.

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